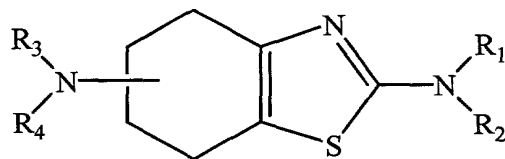


WHAT IS CLAIMED IS:

- 1 1. A method for increasing the efficacy of a therapeutic agent
2 administered to a subject having an autoimmune condition, comprising co-administering
3 to the subject an effective amount of a sleep restorative agent or a pharmacologically
4 acceptable addition salt thereof, and a therapeutic agent;
5 whereby the efficacy of the therapeutic agent is increased.
- 1 2. The method of claim 1, wherein an undesired side effect associated
2 with administration of the therapeutic agent is reduced.
- 1 3. The method of claim 1, wherein a symptom of the subject is
2 reduced.
- 1 4. The method of claim 1, wherein administration of the sleep
2 restorative agent spares the effective amount of the therapeutic agent.
- 1 5. The method of claim 1, wherein sleep quality of the subject is
2 increased.
- 1 6. The method of claim 5, wherein increased sleep quality is
2 manifested by restoration or prolongation of stage III/IV sleep, decreased sleep
3 fragmentation or disruption, reduced sleep apnea, reduced restless legs syndrome,
4 decreased restlessness, decreased racing thoughts, decreased talking in one's sleep or
5 decreased nightmares.
- 1 7. The method of claim 1, wherein excessive sympathetic tone in the
2 subject is reduced.
- 1 8. The method of claim 1, wherein the sleep restorative agent is a
2 compound of the following formula:



(I)

wherein

R₁ represents a hydrogen atom, a C₁₋₆ alkyl group, a C₃₋₆ alkenyl, a C₃₋₆ alkynyl, a C₁₋₆ alkanoyl group, a phenyl C₁₋₃ alkyl group, or a phenyl C₁₋₃ alkanoyl group, wherein the phenyl nuclei may be substituted by 1 or 2 halogen atoms;

R₂ represents a hydrogen atom or a C₁₋₄ alkyl group;

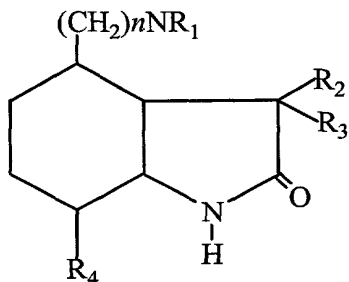
R₃ represents a hydrogen atom, a C₁₋₇ alkyl group, a C₃₋₇ cycloalkyl group, a C₃₋₆ alkenyl group, a C₃₋₆ alkynyl group, a C₁₋₇ alkanoyl group, a phenyl C₁₋₃ alkyl, or a phenyl C₁₋₃ alkanoyl group, wherein the phenyl nucleus may be substituted by fluorine, chlorine or bromine atoms;

R₄ represents a hydrogen atom, a C₁₋₄ alkyl group, a C₃₋₆ alkenyl group, or a C₃₋₆ alkynyl group; or

R₃ and R₄ together with the nitrogen atom between them represent a pyrrolidino, piperidino, hexamethyleneimino or morpholino group.

9. The method of claim 8, wherein the sleep restorative agent is 2-amino-4,5,6,7-tetrahydro-6-(propylamino)benzo-thiazole or the (-)-enantiomer thereof.

10. The method of claim 1, wherein the sleep restorative agent is a compound of the following formula:



(II)

3 wherein
4 R₁ is hydrogen or a C₁₋₄ alkyl group;
5 R₂ and R₃ are each hydrogen or a C₁₋₄ alkyl group;
6 R₄ is hydrogen or hydroxy; and
7 n is 1 to 3.

1 11. The method of claim 10, wherein the sleep restorative agent is 4-[2-
2 (dipropylamino)-ethyl]-1,3-dihydro-2H-indol-2-one.

1 12. The method of claim 1, wherein the sleep restorative agent is
2 Lorazepam, Clonazepam, Tizanidine, Gabapentin, Zaleplon, Zolpidem, pregabalin, or
3 pharmaceutically acceptable salts thereof.

1 13. The method of claim 1, wherein the therapeutic agent is soluble
2 TNF α receptor, methotrexate, prednisone, an interferon, a cyclosporin, an ascomycin, a
3 rapamycin, a corticosteroid, a cyclophosphamide, azathioprine, brequinar, leflunomide,
4 mizoribine, deoxyspergualin, or immunosuppressive monoclonal antibodies to a leukocyte
5 receptor.

1 14. The method of claim 13, wherein the soluble TNF α receptor is
2 Etanercept or Lenercept.

1 15. The method of claim 1, wherein the sleep restorative agent and the
2 therapeutic agent are administered in a unitary dosage form.

1 16. The method of claim 1, wherein the sleep restorative agent and the
2 therapeutic agent are administered separately.

1 17. The method of claim 1, wherein the sleep restorative agent is
2 administered as a dosage form of a tablet, capsule, lozenge, powder, solution, suspension,
3 emulsion, injectable solution, syrup, suppository, or transdermal patch.

1 18. The method of claim 17, wherein the dosage form further comprises
2 a pharmaceutically acceptable carrier.

1 19. The method of claim 1, wherein the therapeutic agent is an
2 immunomodulatory agent.

1 20. A method for sparing an effective amount of a therapeutic agent
2 administered to a subject having an autoimmune condition, comprising:
3 co-administering to the subject the therapeutic agent and an effective
4 amount of a sleep restorative agent, the sleep restorative agent improving sleep quality of
5 the subject;
6 whereby the sleep restorative agent spares the effective amount of the
7 therapeutic agent.

1 21. The method of claim 20, wherein an undesired side effect associated
2 with administration of the therapeutic agent is reduced.

1 22. The method of claim 20, wherein the autoimmune condition is
2 rheumatoid arthritis; psoriatic arthritis; a spondyloarthropathy; palindromic rheumatism;
3 systemic lupus erythematosus; vasculitis with systemic lupus erythematosus; multiple
4 sclerosis; Hashimoto's thyroiditis; chronic pseudogout; hepatitis C arthritis, mixed
5 connective tissue disease; dermatomyositis, polymyositis; scleroderma; Sjogren's
6 syndrome; cryoglobulinemia; Crohn's disease; ulcerative colitis; autoimmune hepatitis;
7 sclerosing cholangitis; primary biliary cirrhosis; autoimmune pneumonitis; autoimmune
8 cerebritis; thyroiditis; graft versus host disease; Myasthenia gravis; pemphigus vulgaris;
9 temporal arteritis; polymyalgia rheumatica; autoimmune hemolytic anemia; idiopathic
10 thrombocytopenic purpura; thrombotic thrombocytopenic purpura; hemolytic uremic
11 syndrome; Sweet's syndrome; polyarteritis nodosa; microscopic polyarteritis nodosa;
12 amyloidosis; sarcoidosis; or familial Mediterranean fever.

1 23. The method of claim 22, wherein the spondyloarthropathy is
2 Behcet's disease, Whipple's Disease, sarcoidosis, ankylosing spondylitis or Reiter's
3 Syndrome.

1 24. A method for sparing an effective amount of a therapeutic agent
2 administered to a subject having an autoimmune condition, comprising:

3 co-administering to the subject the therapeutic agent and an effective
4 amount of a sleep restorative agent, the sleep restorative agent reducing excessive
5 sympathetic tone of the subject;
6 whereby the sleep restorative agent spares the effective amount of the
7 therapeutic agent.

1 25. A method for reducing a symptom in a subject in need of
2 immunomodulatory therapy, comprising co-administering an effective amount of an
3 immunomodulatory agent and an effective amount of a sleep restorative agent, the sleep
4 restorative agent improving sleep quality of the subject;
5 whereby the sleep restorative agent spares the effective amount of the
6 immunomodulatory agent needed to reduce the symptom.

1 26. The method of claim 25, wherein the immunomodulatory agent is
2 soluble TNF α receptor, prednisone, methotrexate, an interferon, a cyclosporin, an
3 ascomycin, a rapamycin, a corticosteroid, a cyclophosphamide, azathioprine, brequinar,
4 leflunomide, mizoribine, deoxyspergualin, or immunosuppressive monoclonal antibodies
5 to a leukocyte receptor.

1 27. The method of claim 26, wherein the immunomodulatory agent is
2 soluble TNF α receptor.

1 28. The method of claim 25, wherein the subject has a sleep disorder.

1 29. The method of claim 25, wherein a side effect associated with
2 administration of the therapeutic agent is reduced.

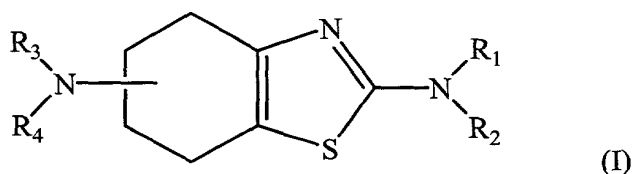
1 30. A composition for administration to a subject having an
2 autoimmune disease, comprising:
3 an effective amount of a sleep restorative agent; and
4 and an effective amount of a therapeutic agent;
5 the effective amount of the therapeutic agent spared by the sleep restorative
6 agent.

1 31. The composition of claim 30, wherein the composition is a unitary
2 dose.

1 32. The composition of claim 30, wherein the composition is
2 administered as a tablet, capsule, lozenge, powder, solution, suspension, emulsion,
3 injectable solution, syrup, suppository, or transdermal patch.

1 33. The composition of claim 30, wherein the composition further
2 comprises a pharmaceutically acceptable carrier, an excipient or an adjuvant.

1 34. The composition of claim 30, wherein the sleep restorative agent is
2 a compound of the following formula:



3
4 wherein

5 R₁ represents a hydrogen atom, a C₁₋₆ alkyl group, a C₃₋₆ alkenyl, a C₃₋₆
6 alkynyl, a C₁₋₆ alkanoyl group, a phenyl C₁₋₃ alkyl group, or a phenyl C₁₋₃ alkanoyl
7 group, wherein the phenyl nuclei may be substituted by 1 or 2 halogen atoms;

8 R₂ represents a hydrogen atom or a C₁₋₄ alkyl group;

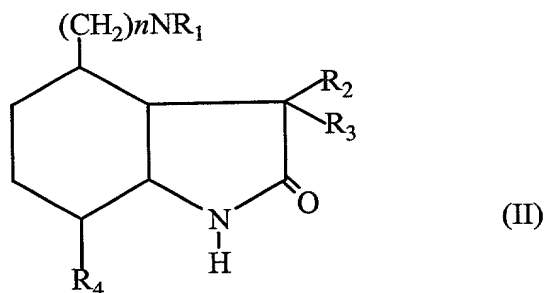
9 R₃ represents a hydrogen atom, a C₁₋₇ alkyl group, a C₃₋₇ cycloalkyl group,
10 a C₃₋₆ alkenyl group, a C₃₋₆ alkynyl group, a C₁₋₇ alkanoyl group, a phenyl C₁₋₃ alkyl, or
11 a phenyl C₁₋₃ alkanoyl group, wherein the phenyl nucleus may be substituted by fluorine,
12 chlorine or bromine atoms;

13 R₄ represents a hydrogen atom, a C₁₋₄ alkyl group, a C₃₋₆ alkenyl group, or
14 a C₃₋₆ alkynyl group; or

15 R₃ and R₄ together with the nitrogen atom between them represent a
16 pyrrolidino, piperidino, hexamethyleneimino or morpholino group.

1 35. The method of claim 34, wherein, wherein the sleep restorative
2 agent is 2-amino-4,5,6,7-tetrahydro-6-(propylamino)benzo-thiazole or the (-)-enantiomer
3 thereof.

1 36. The method of claim 30, wherein the sleep restorative agent is a
2 compound of the following formula:



3
4 wherein

5 R₁ is hydrogen or a C₁₋₄ alkyl group;

6 R₂ and R₃ are each hydrogen or a C₁₋₄ alkyl group;

7 R₄ is hydrogen or hydroxy; and

8 n is 1 to 3.

1 37. The method of claim 36, wherein the sleep restorative agent is 4-[2-
2 (dipropylamino)-ethyl]-1,3-dihydro-2H-indol-2-one.

1 38. The method of claim 30, wherein the sleep restorative agent is
2 Lorazepam, Clonazepam, Tizanidine, Gabapentin, Zaleplon, Zolpidem, or
3 pharmaceutically acceptable salts thereof.

1 39. The method of claim 30, wherein the therapeutic agent is soluble
2 TNF α receptor, methotrexate, prednisone, an interferon, a cyclosporin, an ascomycin, a
3 rapamycin, a corticosteroid, a cyclophosphamide, azathioprine, brequinar, leflunomide,
4 mizoribine, deoxyspergualin, or immunosuppressive monoclonal antibodies to a leukocyte
5 receptor.